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APPLICATION NUMBER: 10/753,424

FILING DATE: January 09, 2004

By Authority of the

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new conprovisional applications under 37 CFR 1.53(b))

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PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN	<u> </u>
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3 8 collection of Information unless it displays a valid OMB control number. Under the Paperwork Reduction Act of 1985, no persons are required to respond to Complete if Known **FEE TRANSMIT** Application Number Filing Date Yosef GROSS First Named Inventor Effective 1010112003. Patent fees are subject to annual revision. Examiner Name Applicant dalms small entity status. See 37 CFR 1.27 Art Unit 1396GIV-US Attorney Docket No. TOTAL AMOUNT OF PAYMENT (5) 425 FEE CALCULATION (continued) METHOD OF PAYMENT (check all that apply) Other None 3. ADDITIONAL FEES Check Credit card Order Order arge Entity Small Entity Deposit Account Fee Fee Code (3) Fee Fee Code (5) Fee Description Fee Paid Deposit Account Number 2051 65 Surcharge -late filing fee or cath 1051 130 2052 25 Surcharge - late provisional filing fee or cover sheet 1052 50 Deposit Account 1053 130 Non-English specification Name 1053 130 Director is authorized to: (check all that apply) 1812 2,520 For filing a request for ex parte reexamination 1812 2,520 Charge fee(s) indicated below Credit any overpayments 1804 9201 1504 920° Requesting publication of SIR prior to Examiner action Charge any additional fae(s) or any underpayment of fee(s) 1805 1,840° Requesting publication of SIR after Examiner action Charge fee(a) indicated below, except for the filing fee 1805 1,840 to the above-identified deposit account. 2251 55 Extension for reply within first month 1251 110 FEE CALCULATION 2252 210 Extension for reply within second month 1252 420 1. BASIC FILING FEE 1263 950 2253 475 Extension for reply within third month arge Entity Small Entity Fee Fee Fee Fee Code (\$) Code (\$) Fee Pald 2254 740 Extension for reply within fourth month 1254 1,480 Fee Fee Code (\$) Fee Description 2255 1,005 Extension for reply within fifth month 1255 2,010 Utility filing fee 1001 770 2001 385 2401 165 Notice of Appeal 1401 330 2002 170 Design filing fee 1002 340 1402 330 2402 165 Filling a brief in support of an appeal Plant filing fee 1003 530 2003 265 2403 145 Request for oral hearing 1403 290 2004 385 Reissua filico fee 1004 770 1451 1,510 Polition to Institute a public use proceeding 1451 1.510 Provisional filing fee 1005 160 2005 80 1452 110 2452 55 Petition to revive - unavoidable SUBTOTAL(1) (5) 385 2453 665 Petition to revive - unintentional 1453 1.330 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE 2501 685 Utility Issue fee (or reissue) 1501 1,330 1502 480 2502 240 Design issue fee Ex<u>tra Cla</u>lma -20-× 1503 640 2503 320 Plant Issue fee Independent Claims Multiple Dependent 1460 130 Patitions to the Commissioner 1480 130 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 Large Entity Fee Fee Code (\$) 1806 180 Submission of Information Disclosure Simt Small Entity 1806 180 Fee Description 8021 40 Recording each patent assignment per property (times number of properties) 8021 40 40 Code (5)

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2809 385 Filing a submission after final rejection (37 CFR 1.129(a))

385 Request for Continued Examination (RCE)

900 Request for expedited examination of a design application

2810 386 For each additional invention to be examined (37 GFR 1.128(b))

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2202 9 Claims in excess of 20

2201 43 Independent claims in excess of 3

2204 43 ** Reissue Independent claims over original patent

2203 145 Multiple dependent claim, if not paid

Reissue claims in excess of 20 and over original patent

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9 January 2004 BY FAX TO: (703) 892-4510

Amy Hunt/Rob Cunningham LANDON & STARK ASSOCIATES One Crystal Park, Suite 210 2011 Crystal Drive Arlington, VA 22202 USA

Re: US Patent Application
PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN
Yossi GROSS et al.
Our Ref: 1396GIV-US

Dear Amy/Rob,

Attached herewith please find the following documents for filing a new patent application today in the USPTO:

- 1. Utility Patent Application Transmittal (1 sheet)
- 2. Fee Transmittal for FY 2004 (1 sheet)
- 3. Credit Card Payment Form (for paying the \$425 fees)
- 4. Declaration and Power of Attorney (2 sheets)
- 5. Assignment papers (3 sheets)
- 5. Drawings (3 sheets)

I am e-mailing you shortly the specification (9 pages). Please submit the application today.

Thank you very much for your fine service.

Sincerely,

David Klein

Dekel Patent Ltd.

Davil Illi

Encl.

Total of 12 pages (including cover letter)

1396giv.doc 8-Jan-04

PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN FIELD OF THE INVENTION

The present invention relates generally to a pressure-propelled system, suitable for imaging body lumens, such as the gastrointestinal (GI) tract.

BACKGROUND OF THE INVENTION

Many imaging devices are known for producing medical images of body lumens, such as the gastrointestinal (GI) tract. For example, endoscopy is widely used for observing, photographing tissue, and taking specimens from lesions and the like. In a conventional method of examining a colon using an endoscope, for example, the endoscope is typically manually inserted into the colon. In this manual technique, patients may often complain of abdominal pain and distention because the colon is extended or excessively dilated, thereby necessitating stopping the endoscopic procedure. Furthermore, it is not unusual for the colon to bleed and be accidentally perforated. Insertion of an endoscope through the sigmoid colon and into the descending colon, or through the splenic flexure, the transverse colon, the hepatic flexure or parts affected by previous operations may also be accompanied with difficulty. Because of these reasons, a colonoscopy is typically performed by a relatively few number of skilled practitioners, and the rate of patient pain and discomfort is high.

US Patent 5,337,732 to Grundfest et al. describes a robot for performing endoscopic procedures, which includes a plurality of segments attached to each other through an articulated joint. Actuators can move the segments together and apart and change their angular orientation to allow the robot to move in an inchworm or snake-like fashion through a cavity or lumen within a patient. Inflatable balloons around the segments inflate to brace a temporarily stationary segment against the lumen walls while other segments move. A compressed gas line attached to the back segment provides compressed gas to inflate the balloons and optionally to drive the actuators. The lead segment includes a television camera and biopsy arm or other sensors and surgical instruments.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved imaging system which is propelled by fluid pressure, suitable for imaging body lumens, such as the gastrointestinal (GI) tract, as is described more in detail hereinbelow. The invention is described hereinbelow

with reference to the GI tract, but it is understood that the invention is not limited to the GI tract and may be used for other body lumens as well. Unlike the prior art, which may inflate and anchor balloons and similar devices to the GI tract wall in an attempt to overcome the low friction of the GI tract, the present invention utilizes the very low friction environment of the GI tract to propel the imaging system, with no need for anchoring.

There is thus provided in accordance with an embodiment of the present invention, a system including a guide member at least partially insertable into a proximal opening of a body lumen, the guide member including a first passageway connectable to a source of fluid pressure, an elongate carrier arranged for sliding movement through the guide member, and a piston head mounted on the carrier, wherein a greater fluid pressure acting on a proximal side of the piston head than on a distal side of the piston head propels the piston head and the carrier in a distal direction in the body lumen.

The system of the invention may have different features. For example, the piston head may be inflatable. The carrier may include a second passageway in fluid communication with the piston head, which may be connected to a source of fluid pressure for inflating the piston head. A vent tube may pass through the piston head, having an opening distal to the piston head through which fluid may be vented to the outside. An image-capturing device may be mounted on the carrier, such as distal to the piston head. A power supply tube may pass through the carrier and may be connected to the image-capturing device. A fluid supply tube may pass through the carrier and may be connected to a fluid source.

In accordance with an embodiment of the present invention an auxiliary piston head may be mounted on the carrier proximal to the first-mentioned piston head. The auxiliary piston head, which may be inflatable, may be fixed axially to the carrier at a fixed distance from the first-mentioned piston head. The carrier may include a third passageway in fluid communication with the auxiliary piston head, which may be connected to a source of fluid pressure for inflating the auxiliary piston head.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a simplified pictorial illustration of a system, constructed and operative in accordance with an embodiment of the present invention, which may be suitable for imaging body lumens, such as the GI tract;

Figs. 2 and 3 are simplified sectional illustrations of distal and proximal portions, respectively, of the system of Fig. 1;

Fig. 4 is a simplified sectional illustration of a carrier of the system of Fig. 1, the section being taken transverse to a longitudinal axis of the carrier; and

Figs. 5, 6 and 7 are simplified pictorial illustrations of the system of Fig. 1, showing three steps of a mode of operation thereof, wherein inflatable piston heads are inflated and deflated to negotiate obstacles in a body lumen.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1-3, which illustrate a system 10, constructed and operative in accordance with an embodiment of the present invention.

As seen best in Fig. 3, system 10 may include a guide member 12, which may be constructed of any medically safe material, such as but not limited to, plastic or metal. Guide member 12 may be formed with a first passageway 14 connected to a source of fluid pressure 16, such as but not limited to, a source of pressurized air, CO₂ or water. Guide member 12 may be at least partially insertable into a proximal opening 18 (e.g., the rectum) of a body lumen 20 (e.g., the colon). Guide member 12 may include an annular ring 22 for abutting against the proximal opening 18.

Guide member 12 may be formed with a bore 24 through which an elongate carrier 26 may be arranged for sliding movement. An O-ring 28 may be provided for dynamically sealing carrier 26 in its sliding motion relative to the guide member 12. Carrier 26 may be any slender wire, catheter or tube and the like, constructed of any medically safe material, such as but not limited to, a flexible plastic or metal. Carrier 26, including its tip, may be safely deflected and steered through the body lumen 20.

A piston head 30 may be mounted on carrier 26. Piston head 30 may be inflatable, and as such may be constructed of any medically safe elastomeric material, such as but not limited to, a bladder or membrane made of polyurethane or silicone rubber, for example. An image-capturing device 32 may be mounted on carrier 26 distal to piston head 30. Piston head 30 is preferably fixed to carrier 26 and sealed thereto with O-rings 33, but optionally

may be arranged to slide on carrier 26 up to some distal stop which arrests further distal motion of the piston head 30 (the image-capturing device 32 may serve as the distal stop, for example). Image-capturing device 32 may comprise, without limitation, a camera (e.g., CCD or CMOS), or alternatively x-ray, ultrasonic, MRI, infrared and/or microwave imaging devices.

Other therapeutic or diagnostic devices may be mounted on or in carrier 26, such as but not limited to, a magnet, drug delivery devices (e.g., iontophoresis), gene therapy devices and others.

The carrier 26 may include a second passageway 34 in fluid communication with piston head 30, connected to a source of fluid pressure 36 (e.g., pressurized air or water) for inflating piston head 30.

A vent tube 38 may pass through piston head 30, having an opening 40 distal to piston head 30 through which fluid is ventable to the outside (that is, the proximal end of vent tube 38 vents the fluid past guide member 12 to the outside). Optionally, the proximal end of vent tube 38 may be connected to a suction source (not shown) for sucking fluid through vent tube 38.

A power supply tube 42 (e.g., containing electrical wires, fiber optics, etc.) may pass through carrier 26, for connection to image-capturing device 32. Alternatively, the electrical and optical components of image-capturing device 32 may have their own internal power source, with no need for external wiring. The image-capturing device 32 may wirelessly transmit or receive data to or from an external processor (not shown). The components of system 10 may be fully automated with sensors and operate in a closed or open control loop.

A fluid supply tube 44 (seen in Fig. 4 only) may pass through carrier 26, which may be connected to a fluid source (not shown), e.g., pressurized water, for cleaning the area near the image-capturing device 32, or in combination with the vent tube 38, for cleaning the body lumen 20 itself (e.g., the colon).

In accordance with an embodiment of the present invention an auxiliary piston head 46 may be mounted on the carrier proximal to the distal piston head 30. The auxiliary piston head 46, which like the piston head 30 may be inflatable, may be fixed axially to carrier 26 at a fixed distance from piston head 30. Auxiliary piston head 46 may be sealed with respect to carrier 26 with O-rings 47. The carrier 26 may include a third passageway 48 in fluid

communication with auxiliary piston head 46, connected to a source of fluid pressure 50 for inflating auxiliary piston head 46.

Reference is now made to Figs. 1, 2 and 5-7, which illustrate operation of the system 10, in accordance with an embodiment of the present invention. The system 10 may be inserted in the rectum with the piston heads 30 and 46 initially deflated to facilitate insertion. The distal piston head 30 may then be gently inflated until it expands to the inner walls of the body lumen (e.g., colon) 20 (the configuration shown in Fig. 1). Pressurized fluid (e.g., air) from the source of fluid pressure 16 may be introduced into the colon through the first passageway 14 of guide member 12. The pressurized fluid creates greater fluid pressure acting on the proximal side of piston head 30 than on the distal side of piston head 30. The vent may assist in creating the pressure difference across the piston head 30. This pressure difference propels piston head 30 together with carrier 26 distally into the body lumen (in this example, the colon), as indicated by arrow 60. Image-capturing device 32 may capture images of the body lumen 20 as the system 10 travels therethrough.

As seen in Fig. 5, the system 10 may eventually reach an obstacle or tight turn, indicated by arrow 62. In such a case, the proximal piston head 46 may be inflated and the distal piston head 30 may be deflated as shown in Fig. 6. In this configuration, the pressurized fluid creates greater fluid pressure acting on the proximal side of the proximal piston head 46 than on the distal side of the proximal piston head 46. This pressure difference propels the proximal piston head 46 together with carrier 26 distally, as indicated by arrow 64. This distal movement brings the distal deflated piston head 30 past the obstacle, as seen in Fig. 6. The system 10 continues its distal movement in the body lumen 20 until the proximal piston head 46 reaches the obstacle. At this point, the distal piston head 30 may be inflated and the proximal piston head 46 may be deflated once again, as shown in Fig. 7. Once again, the pressurized fluid creates greater fluid pressure acting on the proximal side of the distal piston head 30 than on the distal side of the distal piston head 30. The pressure difference propels the system 10 distally in the body lumen 20, and brings the proximal deflated piston head 46 past the obstacle. The cycle may be repeated as often as necessary.

Although the invention has been described in conjunction with specific embodiments thereof, many alternatives, modifications and variations are apparent to those skilled in the

art. Accordingly, all such alternatives, modifications and variations fall within the spirit and scope of the following claims.

7 CLAIMS

What is claimed is:

1. A system comprising:

a guide member at least partially insertable into a proximal opening of a body lumen, said guide member including a first passageway connectable to a source of fluid pressure;

an elongate carrier arranged for sliding movement through said guide member; and

a piston head mounted on said carrier, wherein a greater fluid pressure acting on a proximal side of said piston head than on a distal side of said piston head propels said piston head and said carrier in a distal direction in the body lumen.

- 2. The system according to claim 1, wherein said piston head is inflatable.
- 3. The system according to claim 2, wherein said carrier includes a second passageway in fluid communication with said piston head and connectable to a source of fluid pressure for inflating said piston head.
- 4. The system according to claim 1, further comprising a vent tube passing through said piston head, having an opening distal to said piston head through which fluid is ventable to the outside.
- 5. The system according to claim 1, further comprising an image-capturing device mounted on said carrier.
- 6. The system according to claim 5, wherein said image-capturing device is distal to said piston head.
- 7. The system according to claim 5, further comprising a power supply tube passing through said carrier and connected to said image-capturing device.
- 8. The system according to claim 1, further comprising a fluid supply tube passing through said carrier and connectable to a fluid source.
- 9. The system according to claim 1, further comprising an auxiliary piston head mounted on said carrier proximal to the first-mentioned piston head.
- 10. The system according to claim 9, wherein said auxiliary piston head is fixed axially to said carrier at a fixed distance from the first-mentioned piston head.
- 11. The system according to claim 9, wherein said auxiliary piston head is inflatable.

12. The system according to claim 11, wherein said carrier includes a third passageway in fluid communication with said auxiliary piston head and connectable to a source of fluid pressure for inflating said auxiliary piston head.

ABSTRACT OF THE DISCLOSURE

A system including a guide member at least partially insertable into a proximal opening of a body lumen, the guide member including a first passageway connectable to a source of fluid pressure, an elongate carrier arranged for sliding movement through the guide member, and a piston head mounted on the carrier, wherein a greater fluid pressure acting on a proximal side of the piston head than on a distal side of the piston head propels the piston head and the carrier in a distal direction in the body lumen.

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Attorney Docket No.: 1396GIV-US

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As below named inventors, we hereby declare that:

Our residences, post office addresses and citizenship are as stated below under our names.

We believe that we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled

PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN

X	is attached hereto was filed on as Application Serial No.	
	and was amended on	(if applicable).

We hereby state that we have reviewed and understand the contents of the above-identified Specification, including the claims, as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a).

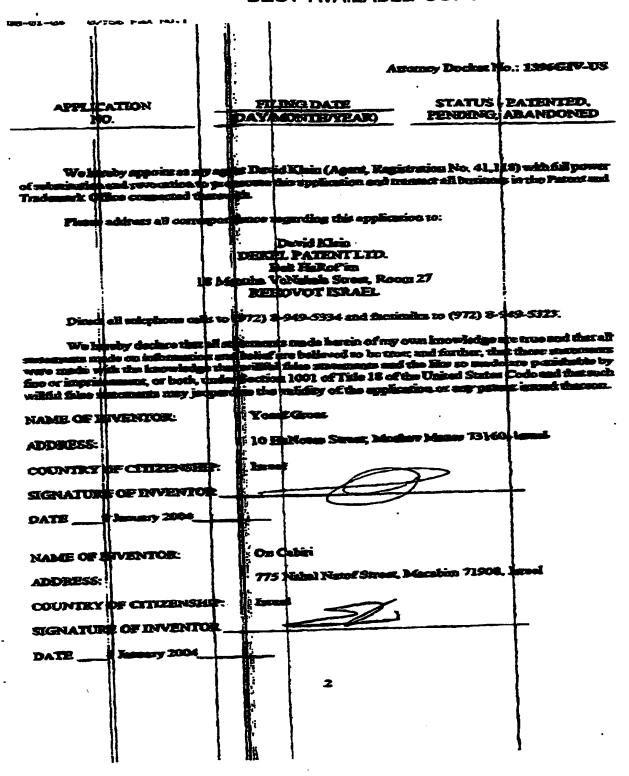
We hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or (f) of any provisional application filed in the United States in accordance with 35 U.S.C. §119(e), or any application for patent that has been converted to a Provisional Application within one (1) year of its filing date, or any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FILED APPLICATION(S)

APPLICATION COUNTRY (DAY/MONTH/YEAR FILED) PRIORITY
NUMBER
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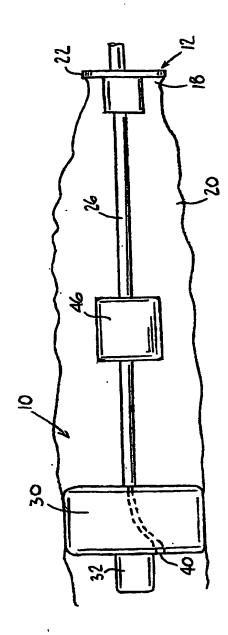
We hereby claim the benefit under Title 35, United States Code, §120 of any United States application listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in any prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a), which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

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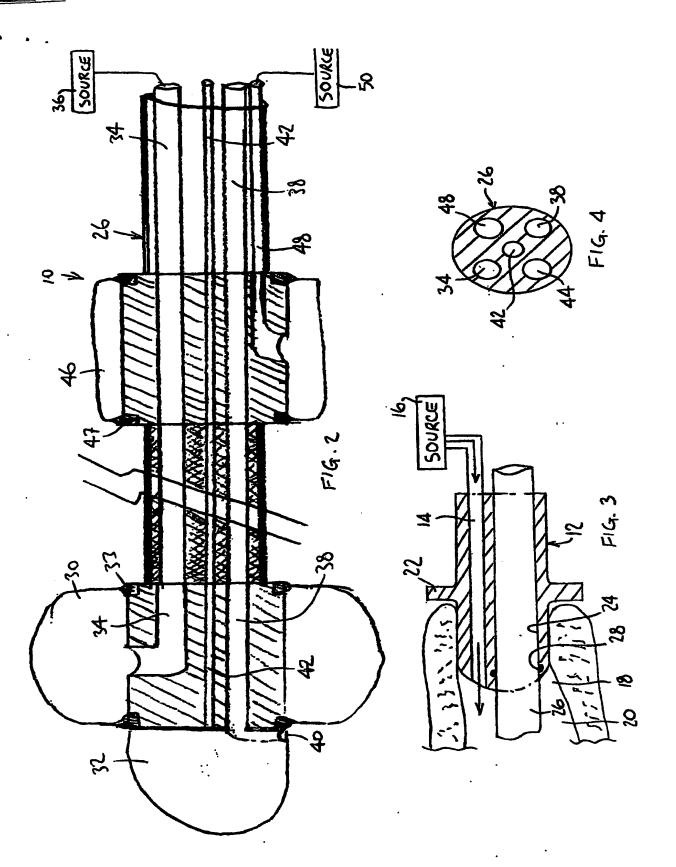


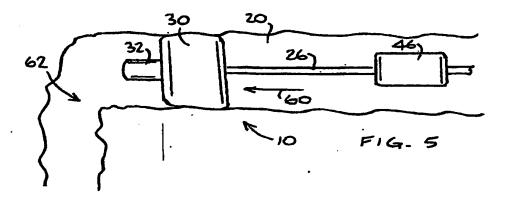
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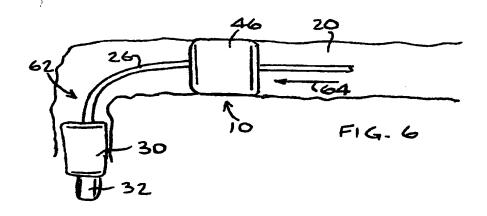
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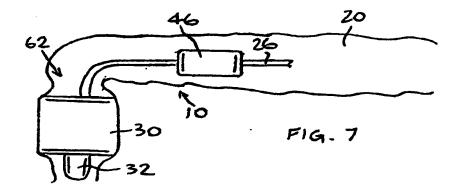


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09 January 2004 (09.01.2004)

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